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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/716,778	11/19/2003	Susan K. Brown-Skrobot	VTN-388CON1	6163

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EXAMINER	
CHORBAJI, MONZER R	

ART UNIT	PAPER NUMBER
1744	

DATE MAILED: 04/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/716,778	BROWN-SKROBOT ET AL.	
	Examiner	Art Unit	
	MONZER R. CHORBAJI	1744	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-50* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-50* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *29 September 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *09/29/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This non-final action is in response to the continuation application filed on 11/19/2003

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

2. The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

3. Claims 20-29 and 42-50 are rejected under 35 U.S.C. 102(e) as being anticipated by Clark et al (U.S.P.N. 5,786,598).

With respect to claims 20 and 42, the Clark reference disclose a process and an apparatus for sterilizing contact lenses (col.3, lines 44-50 and figure 4:64) that include the following: irradiating medical devices to ultraviolet light with a wavelength between 180 nm and 300 nm (col.3, lines 60-65) with a total energy density of 20 mJ/cm^2 (col.8, lines 10-13), radiation source (figure 8:40), reflector (figure 8:22) that is capable of directing the radiation source to the treatment area (figure 1:12 and 20) where a device

is placed for irradiation, treatment area is located at the focal plane of the reflector (focal plane is where the package to be treated is placed in figure 8) and the reflector is capable of directing radiation of 20 mJ/cm^2 in broad spectrum of which at least 50 mJ/cm^2 is UV radiation applied to the treatment area.

With respect to claims 21-29 and 43-50, the Clark reference teaches the following: ultraviolet light with a wavelength between 180 nm and 300 nm (col.3, lines 60-65) with a total energy density of 90 mJ/cm^2 (col.8, lines 10-13) per pulse (col.9, lines 58-61), delivering UV radiation in less than 20 seconds (col.9, lines 59-61), or in less than 1 second (col.9, lines 59-61), or in less than 1 millisecond (col.9, lines 59-61), eliminating wavelengths that damages medical devices (col.3, lines 33-38), the entire hermetically sealed contents are sterilized with UV light (col.7, lines 1-4), the use of flashlamp (figure 7:40), a capacitance (col.10, lines 1-8) that is capable of supplying power of 80 to 160 microFarad and is also capable of generating potential between 2500-6000 volts, more than one radiation source that is capable of being powered in series (figure 8 and col.6, lines 25-27), reflectors (figure 8:22) that are capable of having enhanced reflection in the ultraviolet range and is also capable of minimizing the non-ultraviolet radiation.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 1-12 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clark et al (U.S.P.N. 5,786,598) in view of Matner et al (U.S.P.N. 5,252,484).

With respect to claim 1, the Clark reference discloses a process for irradiating medical devices by using UV light of wavelength between 180 nm and 300 nm (col.3, lines 60-65) and with a total energy density (D_{value}) of 20 mJ/cm^2 (col.8, lines 10-13). However, the Clark reference fails to teach the use of Bacillus stearothermophilus (ATCC 7953). The Matner reference teaches that efficacies of sterilization cycles are determined by the use of (col.1, lines 7-8 and col.2, lines 35-39) Bacillus stearothermophilus (ATCC 7953). As a result it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the Clark reference by irradiating Bacillus stearothermophilus (ATCC 7953) in order to determine the sterilization efficacy since such organisms are recognized as the most resistant form of microbial life (Matner reference, col.5, lines 53-60 and col.6, lines 3-4).

With respect to claims 2-6, the Clark reference teaches the following: providing a sterility assurance level of at least 10^{-6} (col.3, lines 35-37), a wavelength between 180 nm and 300 nm (col.3, lines 60-65) with a total energy density of 90 mJ/cm^2 (col.8, lines 10-13) by at least one pulsed radiation source (col.6, lines 40-41) delivered in less than 1 millisecond (col.9, lines 58-61). However, the Clark reference fails to teach irradiating Bacillus stearothermophilus (ATCC 7953) spores The Matner reference teaches that efficacies of sterilization cycles are determined by the use of (col.1, lines 7-8 and col.2, lines 35-39) Bacillus stearothermophilus (ATCC 7953) spores. As a result it would have been obvious to one having ordinary skill in the art at the time the invention was made

to modify the Clark reference by irradiating Bacillus stearothermophilus (ATCC 7953) spores in order to determine the sterilization efficacy since such organisms are recognized as the most resistant form of microbial life (Matner reference, col.5, lines 53-60 and col.6, lines 3-4).

With respect to claims 7-12 and 14, the Clark reference teaches the following: more than one pulsed radiation source (col.6, lines 40-41) delivered in less than 1 millisecond (col.9, lines 58-61), radiation sources are pulsed substantially simultaneously (col.9, lines 58-61), the use of flash lamps (col.6, lines 25-27), the use of reflectors (col.6, lines 40-42), the inherent fluence of each lamp at the focal plane (focal plane is where the package to be treated is placed in figure 8) is at least of a wavelength value between 180 nm and 300 nm (col.3, lines 60-65) with a total energy density of 90 mJ/cm^2 (col.8, lines 10-13), the radiation is most pulsed three times (col.9, lines 61-64) and the medical device is in a container (figure 4:64).

9. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Clark et al (U.S.P.N. 5,786,598) in view of Matner et al (U.S.P.N. 5,252,484) as applied to claim 1 and further in view of Hagmann et al (U.S.P.N. 5,439,642).

With respect to claim 13, both the Clark reference and the Matner reference fail to teach the use of laser; however, the Hagmann reference, which is in the art of sterilizing contact lenses, teaches irradiating with laser (col.3, lines 5-8). Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute the polychromatic broad spectrum light source of the Clark reference with the laser source of the Hagmann reference since laser can be caused to produce

radiation of specific wavelength, energy density and intensity resulting in improved surface sterilization of contact lenses (col.3, lines 44-53).

10. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Clark et al (U.S.P.N. 5,786,598) in view of Matner et al (U.S.P.N. 5,252,484) as applied to claim 14 and further in view of Shalaby et al (U.S.P.N. 5,422,068).

With respect to claim 15, the Clark reference teaches irradiating contact lenses that are sealed within containers with ultraviolet light having a wavelength between 180 nm and 300 nm (col.3, lines 60-65) with a total energy density range between 10-50000 mJ/cm^2 (col.8, lines 10-13). The container of the Clark reference must necessarily allow UV through it so that contact lenses are sterilized. However, with respect to claim 15, the Clark reference fails to disclose providing an equation for calculating D_{value} for Bacillus stearothermophilus (ATCC 7953). However, the Matner reference teaches that efficacies of sterilization cycles are determined by the use of (col.1, lines 7-8 and col.2, lines 35-39) Bacillus stearothermophilus (ATCC 7953) spores. As a result it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the Clark reference by irradiating Bacillus stearothermophilus (ATCC 7953) spores in order to determine the sterilization efficacy since such organisms are recognized as the most resistant form of microbial life (Matner reference, col.5, lines 53-60 and col.6, lines 3-4).

With respect to claim 15, the Matner reference fails to disclose providing an equation for calculating D_{value} for Bacillus stearothermophilus (ATCC 7953). The Shalaby reference teaches of known mathematical relationship between transmissivity

and D_{values} (col.3, lines 46-57). Also, the Shalaby reference provides D_{value} for Bacillus stearothermophilus (examples 1-6). Thus, result it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the Clark reference by irradiating Bacillus stearothermophilus (ATCC 77953) for their recognition in the sterilization art as the most resistant microorganisms as taught by the Matner reference and for the importance of D values in determining the rate of microorganisms killed (Shalaby reference, col.3, lines 50-53).

11. Claims 16-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clark et al (U.S.P.N. 5,786,598) in view of Matner et al (U.S.P.N. 5,252,484) and Shalaby et al (U.S.P.N. 5,422,068) as applied to claim 15 and further in view of Hagmann et al (U.S.P.N. 5,439,642).

With respect to claim 16, the Clark reference teaches irradiating contact lenses that are sealed within containers with ultraviolet light having a wavelength between 180 nm and 300 nm (col.3, lines 60-65) with a total energy density range between 10-50000 mJ/cm^2 (col.8, lines 10-13). The container of the Clark reference must necessarily allow UV through it so that contact lenses are sterilized. However, with respect to claim 16, the Clark reference fails to disclose D_{value} for Bacillus stearothermophilus (ATCC 7953) and container has a 50% transmissivity to UV light. The Matner reference teaches that efficacies of sterilization cycles are determined by the use of (col.1, lines 7-8 and col.2, lines 35-39) Bacillus stearothermophilus (ATCC 7953) spores. As a result it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the Clark reference by irradiating Bacillus stearothermophilus (ATCC 7953)

spores in order to determine the sterilization efficacy since such organisms are recognized as the most resistant form of microbial life (Matner reference, col.5, lines 53-60 and col.6, lines 3-4).

With respect to claim 16, the Matner reference fails to disclose providing an equation for calculating D_{value} for Bacillus stearothermophilus (ATCC 7953) and the container has a 50% transmissivity to UV light. The Shalaby reference teaches of known mathematical relationship between transmissivity and D_{values} (col.3, lines 46-57). Also, the Shalaby reference provides D_{value} for Bacillus stearothermophilus (examples 1-6). Thus, result it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the Clark reference by irradiating Bacillus stearothermophilus (ATCC 77953) for their recognition in the sterilization art as the most resistant microorganisms as taught by the Matner reference and for the importance of D values in determining the rate of microorganisms killed (Shalaby reference, col.3, lines 50-53).

With respect to claim 16, the Shalaby reference fails to disclose that the container has a 50% transmissivity to UV light. The Hagmann reference teaches that the container (figure 1:5) can include windows that allow electromagnetic radiation or the container can be entirely constructed to be transparent to electromagnetic radiation (col.3, lines 5-22). Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the Clark reference process by substituting the contact lens container with a container that has 50% or more UV light

transmissivity as taught by the Hagmann reference since increasing the UV transmissivity results in less time required for sterilizing contact lenses.

With respect to claims 17-19, the Clark reference sterilizing contact lenses (figure 4:64) that block at least 50% of UV radiation (col.4, lines 12-20) where the container includes an aqueous solution (col.8, lines 1-5).

12. Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Clark et al (U.S.P.N. 5,786,598) as applied to claim 29 and further in view of Little (WO 97/35624).

With respect to claim 30, the Clark reference fails to disclose placing non-preserved aqueous solution in the sealed container; however, the Little reference teaches the use of contact lens soaking solution (page 5, lines 1-3). Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute the contact lens preserving saline solution of the Clark reference with the contact lens soaking solution of the Little reference in order to prevent dehydration of the lenses during irradiation (Little reference, page 5, lines 1-3).

13. Claim 31-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clark et al (U.S.P.N. 5,786,598) in view of Little (WO 97/35624) as applied to claim 30 and further in view of Hagmann et al (U.S.P.N. 5,439,642).

With respect to claims 31-33, the Clark reference discloses container that include thermoplastic material (col.7, lines 42-48), but fails to teach a container having a lid and a cover made up of thermoplastic that is 50% or more UV transmissive in all directions. The Little reference teaches container having a lid and a cover; however, both

references fail to teach a container that is 50% or more UV transmissive in all directions. The Hagmann reference teaches that the container (figure 1:5) can include windows that allow electromagnetic radiation or the container can be entirely constructed to be transparent to electromagnetic radiation (col.3, lines 5-22) in all directions. Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the Clark reference process by substituting the contact lens container with a container that has 50% or more UV light transmissivity as taught by the Hagmann reference since increasing the UV transmissivity results in less time required for sterilizing contact lenses.

14. Claims 35-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clark et al (U.S.P.N. 5,786,598) in view of Little (WO 97/35624) and Hagmann et al (U.S.P.N. 5,439,642) as applied to claim 34 and further in view of Osipo et al (U.S.P.N. 5,271,874).

With respect to claim 35, the Clark reference teaches moving contact lens containers into a UV sterilization chamber (figure 1, col.5, lines 61-62), but fails to teach forming contact lenses. The Little reference and the Hagmann reference both fail to teach forming contact lenses; however, the Osipo reference teaches a method of forming contact lenses (col.1, lines 6-21). Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the Clark reference process by including a contact lens forming step since incorporating this step into the Clark process results in decreasing the amount of time needed to produce

sterilized containers with contact lenses within without waiting for preformed lens containers to be delivered to the UV sterilization production site.

With respect to claims 36-41, the Clark reference teaches the following: sterilizing contact lenses containers with UV light having a wavelength between 180 nm and 300 nm (col.3, lines 60-65) with a total energy density of 20 mJ/cm^2 (col.8, lines 10-13), contact lens includes UV-blocker that blocks more than 50% of the radiation (col.4, lines 15-20), two flash lamps (col.6, lines 25-28) that flashes simultaneously (col.9, lines 57-62) and flash lamps that deliver a total energy density range between 10-50000 mJ/cm^2 (col.8, lines 10-13) per flash.

Remarks

15. This action is made non-final since the Hagmann et al reference applied now was not part of the record.

Conclusion

16. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The Shalaby et al (U.S.P.N. 5,422,068) reference discloses how the D_{value} is calculated. The Dunn et al (U.S.P.N. 4,910,942) reference teaches the use of polychromatic, incoherent light applied in pulses in the art of sterilization.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MONZER R. CHORBAJI whose telephone number is (571) 272-1271. The examiner can normally be reached on M-F 9:00-5:30.

18. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, GLADYS J. CORCORAN can be reached on (571) 272-1214. The fax

phone number for the organization where this application or proceeding is assigned is 571-273-8300.

19. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

GLADYS J.P. CORCORAN
PRIMARY EXAMINER

Monzer R. Chorbaji MRC
Patent Examiner
AU 1744
03/17/2006